

1 METHODS FOR THE ENDOLUMINAL TREATMENT OF
2 GASTROESOPHAGEAL REFLUX DISEASE (GERD)
3

4 This application is related to co-owned application Serial
5 Number --/---,---, (Docket #SYN-039A) filed simultaneously
6 herewith, entitled "Flexible Surgical Clip Applier", the complete
7 disclosure of which is hereby incorporated by reference herein.
8

9 This application is a continuation-in-part of application
10 Serial Number 09/931,528, filed August 16, 2001, entitled "Methods
11 and Apparatus for Delivering a Medical Instrument Over an
12 Endoscope while the Endoscope is in a Body Lumen", the complete
13 disclosure of which is hereby incorporated by reference herein.
14

15 This application is also a continuation-in-part of
16 application Serial Number 09/891,775, filed June 25, 2001,
17 entitled "Surgical Clip", the complete disclosure of which is .
18 hereby incorporated by reference herein.
19

20 This application also claims the benefit of provisional
21 application Serial Number 60/292,419, filed May 21, 2001, entitled
22 "Methods and Apparatus for On-Endoscope Instruments
23 Having End Effectors and Combinations of On-Endoscope
24 and Through-Endoscope Instruments".
25

1 This application is also a continuation-in-part of
2 application Serial Number 09/730,911, filed December 6, 2000,
3 entitled "Methods and Apparatus for the Treatment of Gastric
4 Ulcers", the complete disclosure of which is hereby incorporated
5 by reference herein.

6 7 BACKGROUND OF THE INVENTION

8 9 1. Field of the Invention

10 The invention relates to endoscopic surgical procedures.
11 More particularly, the invention relates to procedures for the
12 transoral invagination and fundoplication of the stomach to the
13 esophagus.

14 15 2. State of the Art

16 Gastroesophageal fundoplication is a procedure for the
17 treatment of gastroesophageal reflux disease (GERD), a condition
18 in which gastric acids are regurgitated into the esophagus
19 resulting in one or more of esophagitis, intractable vomiting,
20 asthma, and aspiration pneumonia. The fundoplication procedure
21 involves wrapping the fundus of the stomach around the lower end
22 of the esophagus and fastening it in place. Traditionally, this
23 procedure is accomplished via open surgery with the use of sutures
24 to secure the plicated fundus of the stomach around the esophagus
25 without penetrating (incising) the stomach. Although traditional

1 fundoplication involves plicating the fundus and the esophagus, as
2 used herein the term includes plicating the fundus to itself near
3 the esophagus.
4

5 U.S. Patent Number 5,403,326 to Harrison et al. discloses a
6 method of performing endoscopic fundoplication using surgical
7 staples or two-part surgical fasteners. The procedure disclosed
8 by Harrison et al. involves performing two percutaneous endoscopic
9 gastrotomies (incisions through the skin into the stomach) and the
10 installation of two ports through which a stapler, an endoscope,
11 and an esophageal manipulator (invagination device) are inserted.
12 Under view of the endoscope, the esophageal manipulator is used to
13 pull the interior of the esophagus into the stomach. When the
14 esophagus is in position, with the fundus of the stomach plicated,
15 the stapler is moved into position around the lower end of the
16 esophagus and the plicated fundus is stapled to the esophagus.
17 The process is repeated at different axial and rotary positions
18 until the desired fundoplication is achieved. While, the
19 procedure disclosed by Harrison et al. is a vast improvement over
20 open surgery, it is still relatively invasive requiring two
21 incisions through the stomach.
22

23 U.S. Patent Number 5,571,116 to Bolanos et al. discloses a
24 non-invasive treatment of gastroesophageal reflux disease which
25 utilizes a remotely operable invagination device and a remotely

1 operable surgical stapler, both of which are inserted transorally
2 through the esophagus. According to the methods disclosed by
3 Bolanos et al., the invagination device is inserted first and is
4 used to clamp the gastroesophageal junction. The device is then
5 moved distally, pulling the clamped gastroesophageal junction into
6 the stomach, thereby invaginating the junction and involuting the
7 surrounding fundic wall. The stapler is then inserted transorally
8 and delivered to the invaginated junction where it is used to
9 staple the fundic wall.

10 Bolanos et al. disclose several different invagination
11 devices and several different staplers. Generally, each of the
12 staplers disclosed by Bolanos et al. has an elongate body and a
13 spring biased anvil which is rotatable approximately 15 degrees
14 away from the body in order to locate the invaginated
15 gastroesophageal junction between the body and the anvil. The
16 body contains a staple cartridge holding a plurality of staples,
17 and a staple firing knife. Each of the invagination devices
18 disclosed by Bolanos et al. has a jaw member which is rotatable at
19 least 45 degrees and in some cases more than 90 degrees to an open
20 position for grasping the gastroesophageal junction. One of the
21 chief disadvantages of the methods and apparatus disclosed by
22 Bolanos et al. is that the stapler and the invagination device
23 must both be present in the esophagus at the same time. With some
24 of the embodiments disclosed, the presence of both instruments is
25

1 significantly challenged by the size of the esophagus. In
2 addition, the actuating mechanism of the device disclosed by
3 Bolanos et al. is awkward. In particular, the stapler anvil is
4 biased to the open position, and it is not clear whether or not
5 the stapler anvil can be locked in a closed position without
6 continuously holding down a lever. In addition, it appears that
7 the staple firing trigger can be inadvertently operated before the
8 anvil is in the closed position. This would result in inadvertent
9 ejection of staples into the stomach or the esophagus of the
10 patient.

11
12 U.S. Patent Number 6,086,600 to Kortenbach discloses an
13 endoscopic surgical instrument including a flexible tube, a
14 grasping and fastening end effector coupled to the distal end of
15 the tube, and a manual actuator coupled to the proximal end of the
16 tube. The manual actuator is coupled to the end effector by a
17 plurality of flexible cables which extend through the tube. The
18 tube contains a lumen for receiving a manipulable endoscope and
19 the end effector includes a passage for the distal end of the
20 endoscope. The end effector has a store for a plurality of male
21 fastener parts, a store for a plurality of female fastener parts,
22 a rotatable grasper, a rotatable fastener head for aligning a
23 female fastener part and a male fastener part with tissues
24 therebetween, and a firing member for pressing a male fastener
25 part through tissues grasped by the grasper and into a female

1 fastener part. According to a stated preferred embodiment, the
2 overall diameters of the flexible tube and the end effector (when
3 rotated to the open position) do not exceed approximately 20 mm so
4 that the instrument may be delivered transorally to the fundus of
5 the stomach.

6
7 While transoral invagination and fundoplication apparatus and
8 procedures have improved over the years, it is still difficult to
9 deliver and manipulate the necessary apparatus transorally. The
10 primary reason for the difficulty is that the overall diameter, or
11 more accurately the cross sectional area, of the equipment is too
12 large. Notwithstanding Kortenbach's reference to 20mm, most of
13 the equipment in use today is at least 24mm in diameter.
14 Moreover, even if the equipment could be reduced to 20mm in
15 diameter (314 mm² cross sectional area), it would still be
16 difficult to manipulate. Those skilled in the art will appreciate
17 that larger instruments are less pliable and that the invagination
18 and fundoplication procedure requires that the instruments turn
19 nearly 180 degrees. Moreover, it will be appreciated that large
20 instruments obscure the endoscopic view of the surgical site.

21
22 Still other issues which need to be addressed in this
23 procedure include the need to suitably grasp the fundus before
24 plication so that all layers of the fundus are plicated.

1 Preferably, plication damages the fundus so that adhesion occurs
2 during healing.

3
4 3. Co-owned Technology

5 Previously incorporated application Serial Number 09/730,911,
6 filed December 6, 2000, entitled "Methods and Apparatus for the
7 Treatment of Gastric Ulcers", discloses a surgical tool which is
8 delivered to a surgical site over an endoscope rather than through
9 the working lumen of an endoscope.

10
11 Co-owned provisional application Serial Number 60/292,419,
12 filed May 21, 2001, entitled "Methods and Apparatus for On-
13 Endoscope Instruments Having End Effectors and Combinations of On-
14 Endoscope and Through-Endoscope Instruments", discloses many tools
15 and procedures including an on-scope grasper assembly having
16 grasping jaws, and a through-scope clip applier having jaws
17 adapted to close about tissue and apply a clip over and/or through
18 the tissue. In operation, the grasper jaws may grab and hold
19 tissue, e.g., the fundus of the stomach or esophageal tissue,
20 while the jaws of the clip applier surround a portion of the
21 tissue held by the grasper jaws and apply a clip thereover.

22
23 Previously incorporated application Serial Number 09/891,775,
24 filed June 25, 2001, entitled "Surgical Clip", discloses a
25 surgical clip having a U-shaped configuration with first and

1 second arms, and a bridge portion therebetween. The first arm is
2 provided with a tip preferably having a catch, and the second arm
3 extends into a deformable retainer having a tissue-piercing end
4 and preferably also a hook. During application, tissue is
5 clamped, and the clip is forced over the clamped tissue and the
6 retainer of the second arm is bent and may be pierced through the
7 tissue. The retainer is toward and around or adjacent the tip of
8 the first arm preferably until the hook is engaged about the catch
9 to secure the clip to the tissue and prevent the clip and tissue
10 from separating. The clip is provided with structure that
11 facilitates the stacking of a plurality of clips in a clip chamber
12 of a clip applier.
13

14 Previously incorporated application Serial Number 09/931,528,
15 filed August 16, 2001, entitled "Methods and Apparatus for
16 Delivering a Medical Instrument Over an Endoscope while the
17 Endoscope is in a Body Lumen", discloses methods and apparatus for
18 delivering a medical instrument over the exterior of an endoscope
19 while the endoscope is installed in the patient's body in order to
20 allow the use of instruments which are too large to fit through
21 the lumina of an endoscope.
22

23 The previously incorporated simultaneously filed application
24 entitled "Flexible Surgical Clip Applier", discloses a surgical
25 clip applier having a pair of clip applying jaws at the distal end

1 of an outer coil, a set of pull wires extending through the outer
2 coil and coupled to the jaws, and a push wire extending through
3 the outer coil. A clip chamber is provided in the distal end of
4 the coil. A clip pusher is provided at a distal end of the push
5 wire, and adapted to advance a clip into the jaws. The jaws
6 include clamping surfaces which operate to compress tissue between
7 the jaws when the jaws are closed, channels in which a distalmost
8 clip rides when the jaws are closed and the pusher is advanced
9 thereby causing the distalmost clip to be pushed over the tissue,
10 and distal anvil portions which operate to bend a portion of the
11 distalmost clip to facilitate its retention on the clamped tissue.
12 The clip applier is capable of providing a pushing force far in
13 excess of a perceived possible maximum of the 200 grams (0.44 lbs)
14 published in the art. One embodiment of the device of the
15 invention provides a pushing force in excess of 2267 grams (5
16 lbs).
17

18 SUMMARY OF THE INVENTION

19
20 It is therefore an object of the invention to provide methods
21 and apparatus for transoral invagination and fundoplication.
22

23 It is also an object of the invention to provide an apparatus
24 for transoral invagination and fundoplication which is easy to
25 manipulate.

1 It is another object of the invention to provide an apparatus
2 for transoral invagination and fundoplication which has a
3 relatively small cross-sectional area.
4

5 It is still another object of the invention to provide
6 methods and apparatus for fundoplication which combine the
7 relative advantages of staples and two-part fasteners, i.e. the
8 small size of a staple and the greater integrity of a two-part
9 fastener.

10
11 It is yet another object of the invention to provide methods
12 and apparatus for transoral invagination and fundoplication which
13 damages tissue such that adhesion occurs during healing.
14

15 In accord with these objects which will be discussed in
16 detail below, the methods of the invention include delivering a
17 grasper, a clip applier, and an endoscope transorally to the site
18 of fundoplication; grasping the fundus with the grasper (or
19 similar device, e.g. corkscrew) and pulling it into the jaws of
20 the clip applier; closing the jaws of the clip applier over the
21 fundus and applying a clip to the fundus. The method is repeated
22 at different locations until the desired fundoplication is
23 achieved. The apparatus of the invention includes a clip applier
24 having sharp toothed jaws for grasping and damaging the fundus
25 prior to applying the clip. The clip applier has an overall

1 diameter of less than 7mm and may be delivered through a 7mm
2 sleeve which attaches to a 12mm endoscope having a lumen through
3 which the grasper is delivered. The overall cross-sectional area
4 of the apparatus is therefore approximately 152 mm² as compared to
5 the 314mm² of the prior art devices. Alternatively, the clip
6 applier and the grasper may be delivered through an endoscope
7 having two 6mm lumina.

8
9 According to a presently preferred embodiment, the clip
10 applier jaws are coupled to a pull wire via a linkage which
11 increases the mechanical advantage and thus permits greater
12 grasping force.

13
14 A plurality of clip designs are provided. Some embodiments
15 include a pair of arms coupled by a bridge and a single locking
16 retainer. Other embodiments include dual parallel coiled
17 retainers. According to one embodiment, the clip has two
18 detachable retainers which are installed in the fundus and the
19 clip arms and bridge are removed.

20
21 Additional objects and advantages of the invention will
22 become apparent to those skilled in the art upon reference to the
23 detailed description taken in conjunction with the provided
24 figures.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side elevational view of a clip applier according to the invention;

Figure 2 is a side elevational view of a first embodiment of the distal end of the clip applier with the jaws in the closed position;

Figure 3 is a side elevational view of a first embodiment of the distal end of the clip applier with the jaws in the open position;

Figure 4 is a broken isometric view of a first embodiment of the distal end of the clip applier with one jaw removed;

Figure 5 is a broken isometric view of a second embodiment of the distal end of the clip applier with a clip of the type shown in Figures 19 and 20;

Figure 6 is an isometric view of a single jaw of the second embodiment of the distal end of the clip applier;

Figure 7 is a proximal end view of the jaw of Figure 6;

1 Figure 8 is a proximal end view of the two jaws of a second
2 embodiment of the distal end of the clip applier in the closed
3 position with the lower jaw shaded for clarity;
4

5 Figure 9 is a broken isometric view of a third embodiment of
6 the distal end of the clip applier suitable for use with a clip of
7 the type shown in Figures 17 and 18 or 24;
8

9 Figures 10-14 are schematic views illustrating a method
10 according to the invention;
11

12 Figure 15 is a diagram illustrating the comparative cross-
13 section of the instruments used in the method illustrated in
14 Figures 5-10 and a typical prior art instrument;
15

16 Figure 16 is a cross-sectional view of a dual lumen endoscope
17 which can be used in performing the methods of the invention;
18

19 Figure 17 is a side elevational view of a first embodiment of
20 a clip according to the invention prior to application;
21

22 Figure 18 is a side elevational view of the clip of Figure 17
23 after application;
24

1 Figure 19 is a side elevational view of a second embodiment
2 of a clip according to the invention prior to application;

3
4 Figure 20 is a side elevational view of the clip of Figure 19
5 after application;

6
7 Figure 21 is a side elevational view of a third embodiment of
8 a clip according to the invention prior to assembly;

9
10 Figure 22 is a side elevational view of the clip of Figure 21
11 assembled prior to application;

12
13 Figure 23 is a side elevational view of the applied portion
14 of the clip of Figures 17 and 18; and

15
16 Figure 24 is a view similar to Figure 23 of an alternate
17 third embodiment of the applied portion of a clip according to the
18 invention.

1 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

2
3 Referring now to Figure 1, a clip applier 10 according to the
4 invention generally includes a flexible wound outer coil 12 having
5 a proximal end 14 and a distal end 16. An end effector assembly
6 18 is coupled to the distal end 16 of the coil 12 and an actuator
7 assembly 20 is coupled to the proximal end 14 of the coil 12. A
8 plurality of pull/push wires 58, 60 (shown and described below
9 with reference to Figures 2-4) extend through the coil 12 and
10 couple the end effector assembly 18 to the actuator assembly 20.
11 The clip applier 10 is similar to the clip applier described in
12 detail in previously incorporated co-owned application Serial
13 Number --/--, ---, entitled "Flexible Surgical Clip Applier",
14 filed simultaneously herewith. However, in this application, the
15 end effector assembly 18 is designed specifically for
16 fundoplication using a clip significantly larger than that used in
17 the clip applier of the aforesaid co-owned application.

18
19 Figures 2-4 illustrate the details of the end effector
20 assembly 18 according to a first embodiment of the invention. The
21 end effector assembly 18 includes a pair of jaws 22, 24 which are
22 rotatably coupled to a clevis 26. In particular, the clevis 26
23 has a central channel 28 (seen best in Figure 4) which is defined
24 by clevis arms 30, 32. Although the term "clevis" is used because
25 of its general acceptance in the art of endoscopic instruments,

1 the "clevis" 26 is preferably covered on top and bottom so that
2 the only exit from the channel 28 is at the distal end. The jaw
3 22 is rotatably coupled to the clevis arm 30 by an axle 34 and the
4 jaw 24 is rotatably coupled to the clevis arm 32 by an axle 36.
5 The axles 34 and 36 are dimensioned such that they do not
6 significantly obscure the channel 28.

7
8 The jaws 22, 24 are substantially identical. Each jaw 22, 24
9 includes a proximal tang 38, 40, a mounting bore 42, 44, a distal
10 hook shaped anvil 46, 48 and a plurality of medial teeth 50, 52.
11 As seen best in Figure 4, the medial teeth 50, 52 are arranged on
12 one side of the jaw and a short wall 51, 53 is arranged on the
13 opposite side of the jaw to define a groove (or guiding channel)
14 54, 56. The grooves 54, 56 meet the anvils 46, 48 each of which
15 which has a helical surface. The interior (proximal) helical
16 surfaces of the anvils act to bend the clip retainers as described
17 below with reference to Figures 19-24.

18
19 The proximal tang 38, 40 of each jaw is coupled to a
20 respective pull/push wire 58, 60 via two links 62, 64 and 66, 68.
21 The links 62, 66 are substantially L-shaped and are rotatably
22 coupled near their elbow to the clevis arms 30, 32 by axles 70, 72
23 which do not significantly obscure the channel 28 between the
24 clevis arms. One end of the link 62, 66 is coupled to the
25 pull/push wire 58, 60 and the other end of the link 62, 66 is

1 rotatably coupled to one end of the link 64, 68. The other end of
2 the link 64, 68 is rotatably coupled to the tang 38, 40. The
3 combined coupling of each jaw 22, 24 to each pull/push wire 58, 60
4 forms a linkage which amplifies the force from the pull/push wires
5 to the jaws. In particular, as the jaws close, the mechanical
6 advantage increases.

7
8 The proximal ends of the pull/push wires 58, 60 are coupled
9 to the actuator assembly (20 in Figure 1) as described in
10 previously incorporated co-owned application Serial Number --/---
11 ,---, entitled "Flexible Surgical Clip Applier", filed
12 simultaneously herewith.

13
14 A clip pusher (not shown) disposed in the interior of the
15 coil is coupled to a push wire (not shown) which is coupled to the
16 actuator assembly as described in previously incorporated co-owned
17 application Serial Number --/---,---, entitled "Flexible Surgical
18 Clip Applier", filed simultaneously herewith. Unlike the
19 previously incorporated co-owned application, the jaws of the
20 instant clip applier are significantly longer and designed for use
21 with clips approximately 17-20mm long (after the clip is applied)
22 as compared to the 5-7mm clips shown in the previously
23 incorporated co-owned application.

Turning now to Figures 5-8, a second embodiment of the jaws 22', 24' is illustrated. The jaws 22', 24' are substantially identical to each other and are designed for use with any of the clips illustrated in Figures 19-24. Each jaw 22', 24' includes a proximal tang 38', 40', a mounting bore 42', 44', a distal hook shaped anvil 46', 48' and a plurality of medial teeth 50', 52'. The medial teeth 50', 52' are arranged on one side of the jaw and a short wall 51', 53' is arranged on the opposite side of the jaw to define a groove (or guiding channel) 54', 56'. The grooves 54', 56' meet the interior surfaces of the anvils 46', 48' which curve about a single axis. The interior surfaces of the anvils act to bend the clip retainers as described below with reference to Figures 19-24 and as shown by the clip 310 in Figure 5. According to this embodiment, as seen best in Figures 6-8, the guiding channels 54', 56' and the anvils 46', 48' are angled relative to the vertical axis of the jaw 22', 24'. This angle causes the clip to twist as it is pushed through the jaws so that the ends of the clip are offset as shown in Figure 5, for example. According to the presently preferred embodiment, the guiding channels 54', 56' and the anvils 46', 48' are angled approximately 22° relative to the vertical axis of the jaw 22', 24'. According to a method of the invention, clips for use with this embodiment of the jaws are prebent in the bridge area to facilitate movement through the angled channels.

1 Referring now to Figure 9, a third embodiment of the jaws
2 22", 24" is illustrated. The jaws 22", 24" are not identical to
3 each other and are designed for use with clips of the type
4 illustrated in Figures 17-18. Each jaw 22", 24" includes a
5 proximal tang 38", 40" and a mounting bore 42", 44". One jaw 22"
6 terminates with two spaced apart distal hooks 46", 47" and has two
7 rows of medial teeth 50". The other jaw 24" terminates with a
8 single distal hook shaped anvil 48" and has two rows of medial
9 teeth 52". The medial teeth 50", 52" are arranged on both sides
10 of the jaw and a groove (or guiding channel) 54", 56" lies between
11 the rows of teeth. The groove 54" terminates with an undercut
12 well (not shown) as described in co-owned Serial Number --/---,--,
13 whereas the groove 56" continues on to the interior of the anvil
14 48" which has a surface which curves about a single axis. Those
15 skilled in the art will appreciate that when the jaws are closed,
16 the anvil 48" will reside between the hooks 46" and 47" and the
17 teeth 50" will be interleaved with the teeth 52". The interior
18 surface of the anvil 48" bends the clip retainer as described
19 below with reference to Figures 17-18 and as shown and described
20 in previously incorporated co-owned applications Serial Number
21 09/891,775, and Serial Number --/---,---.

22
23 Turning now to Figures 10-14, a method of using the clip
24 applier of the invention is illustrated in context with an
25 existing endoscope 100 having a single lumen through which a small

1 grasper 102 is supplied and an external working channel 104 which
2 is attached to the scope 100 and through which the clip applier is
3 delivered. The external working channel 104 is preferably one of
4 the type described in previously incorporated application Serial
5 Number 09/931,528, filed August 16, 2001, entitled "Methods and
6 Apparatus for Delivering a Medical Instrument Over an Endoscope
7 while the Endoscope is in a Body Lumen".

8
9 According to a method of the invention, after the endoscope
10 assembly is delivered transorally to the procedural site, as shown
11 in Figure 10, the fundus is grasped by the graspers and pulled in
12 between the open jaws of the clip applier. The jaws of the clip
13 applier are then closed onto the invaginated fundus as shown in
14 Figure 11. As the jaws are closed the medial teeth of the jaws
15 puncture the invaginated fundus as shown in Figures 11 and 12.
16 When the jaws are completely closed (or closed as much as
17 possible), they are preferably locked, the grasper is optionally
18 released, and the clip pusher is activated to push forward a clip
19 106 as shown in Figure 12 and as described in the previously
20 incorporated, co-owned, simultaneously filed application and
21 discussed in detail hereinafter.

22
23 After the clip 106 is applied, the jaws of the clip applier
24 are opened as shown in Figure 13 and the clip 106 remains in place
25 and plicates the fundus. Depending on the location of the clip

1 and the nature of the patient's condition, a single clip may be
2 sufficient. If other clips are deemed desirable by the
3 practitioner, the clip applier is removed and re-loaded with
4 another clip. After re-delivering the clip applier, the procedure
5 may be repeated at another location as shown in Figure 14. Given
6 the size of the clips of the invention, anywhere from 1-4 clips
7 will typically be used.

8
9 According to one aspect of the invention, the medial teeth on
10 the jaws of the clip applier are long enough and sharp enough to
11 damage the fundus sufficiently such that when the fundus heals
12 adhesion occurs, binding the plicated fundus to the extent that
13 the clip may no longer be needed. Thus, preferably, the teeth are
14 long enough to pierce all layers of the fundus.

15
16 From the foregoing, those skilled in the art will appreciate
17 that the methods of the invention may be performed with different
18 types of graspers. In particular, alternative grasping devices
19 such as a "cork screw" grasper can be used in conjunction with the
20 clip applier of the invention to perform the methods of the
21 invention.

22
23 It will also be appreciated that the clip applier of the
24 invention may be attached to an endoscope in other ways as
25 described in previously incorporated application Serial Number

1 09/931,528, filed August 16, 2001, entitled "Methods and Apparatus
2 for Delivering a Medical Instrument Over an Endoscope while the
3 Endoscope is in a Body Lumen".
4

5 As mentioned above, the clip applier of the invention has an
6 outside diameter of approximately 6mm. As shown in Figures 10-14,
7 the clip applier is used in conjunction with an endoscope having
8 an outside diameter of approximately 12mm. To accommodate the
9 clip applier, an exterior working channel having an exterior
10 diameter of approximately 7mm is optionally coupled to the
11 endoscope as described in the previously incorporated co-owned
12 applications Serial Numbers 09/931,528 and 60/292,419.
13

14 Figure 15 is a scale representation of the cross-sectional
15 area of the 12mm endoscope 100 with the attached external 7mm
16 working channel 104, shown in horizontal shading. The cross
17 sectional area of a prior art device 108 having an exterior
18 diameter of approximately 24mm is shown in diagonal shading. From
19 Figure 15, it will be appreciated that the methods and apparatus
20 of the invention allow for a substantially smaller device which is
21 more easily delivered transorally and which is more easily
22 manipulated. The overall cross-sectional area of the apparatus of
23 the invention is approximately 152 mm² as compared to the 314mm² of
24 the prior art devices.
25

1 As mentioned, the clip applier of the invention may also be
2 used with a dual lumen endoscope. Figure 16 is a scale
3 representation of a dual lumen endoscope 110 having an optical
4 lumen 112 and two 6mm working lumina 114, 116. As compared to the
5 device 108 in Figure 15, the endoscope 110 has a substantially
6 smaller cross-sectional area than the prior art device.

7
8 The clips used by the clip applier of the invention are
9 substantially longer than the clips described in the previously
10 incorporated co-owned applications, Serial Number 09/891,775 and
11 the simultaneously filed application, which are approximately 7mm
12 in length and adequate for general surgical applications. The
13 retainer portion of the clips of the present invention are
14 substantially longer in order to assure that all of the layers of
15 the fundus are punctured.

16
17 Turning now to Figures 17 and 18, a first embodiment of a
18 surgical clip 210 according to the invention includes first and
19 second arms 212, 214, respectively, and a bridge portion 216
20 therebetween such that the arms and bridge portion are in a
21 generally U-shaped configuration. The first arm 12 is provided
22 with an end catch 220, and the second arm 214 extends (or
23 transitions) into a deformable retainer 222 having a tissue
24 piercing tip 224 and a plurality of catch engagements, e.g. 226,
25 228. The arms define an open space 230 between them. The clip

1 210 is preferably made from a unitary piece of titanium, titanium
2 alloy, stainless steel, tantalum, platinum, other high Z
3 (substantially radiopaque) materials, nickel-titanium alloy,
4 martensitic alloy, or plastic, although other suitable
5 biocompatible materials may be used. The first and second arms
6 212, 214, as well as the bridge portion 216 are relatively stiff
7 and not plastically deformable within the limits of force applied
8 to the arms during use, while the retainer 222 is relatively
9 easily plastically deformable by the clip applier.

10
11 Referring now to Figures 2-4 and 17-18, when the clip 210 is
12 pushed forward in the clip applier with the jaws 22, 24 of the
13 clip applier closed, the retainer 222 is bent across the opening
14 230 between the first and second arms 212, 214 and into engagement
15 with the end catch 220 of the first arm 212 as shown in Figure 18.
16 The anvil formed by the grooves on the interior of the hooks 46,
17 48 of the clip applier jaws guide the bending of the retainer 222
18 causing it to puncture the fundus and couple to the end catch 220.

19
20 The clip 210 shown in Figures 17 and 18 is provided with an
21 optional bendable barb 232 which provides a secondary stabilizing
22 fixation point which helps keep the clip from rotating. As the
23 clip is pushed forward over the fundus, tissue catches the barb
24 232 and bends it as shown in Figure 18.

1 The clip 210 is also provided with an ear 233 on the bridge
2 216. The ear is used by the pushing mechanism (not shown) to
3 grasp the end of the clip when it is loaded into the clip applier.
4

5 A second embodiment of a clip 310 according to the invention
6 is shown in Figures 19 and 20. The clip 310 has two arms 312, 314
7 connected by a bridge 316. Both arms terminate in retainers 320,
8 322, each having a sharp end 321, 323. The clip 310 is also
9 provided with a pair of ears 333, 335 on the bridge 316. The ears
10 are used by the pushing mechanism (not shown) to grasp the end of
11 the clip when it is loaded into the clip applier. This embodiment
12 is intended for use with a clip applier having hooks with interior
13 grooves which diverge, or which are in parallel planes. With
14 reference to Figures 2-4 and 15-16, when the clip 310 is pushed
15 forward, the retainer 320 is bent by the groove inside the hook 46
16 and the retainer 322 is bent by the groove inside the hook 48 to
17 the configuration shown in Figure 20. From Figure 20, it will be
18 appreciated that each retainer punctures the fundus twice
19 substantially forming a circular fastener. Thus, it will also be
20 appreciated that the retainers 320, 322 are significantly longer
21 than the retainer 222 shown in Figures 17 and 18 and preferably
22 are of a length at least π times the distance between the arms
23 312, 314. Insofar as the retainers 320, 322 each form a complete
24 fastener, the function of the arms 312, 314 and the bridge 316 may
25 be considered redundant.

1 Figures 21-23 illustrate a third embodiment of a clip 410
2 according to the invention. The clip 410 is similar to the clip
3 310 (with similar reference numerals increased by 100 referring to
4 similar parts) except that the retainers 420, 422 are removable
5 from the arms 412, 414. The arms 412, 414 terminate in female
6 couplings 413, 415 which receive ends of the retainers 420, 422 in
7 a slight interference fit. The clip 410 is also provided with a
8 pair of ears 433, 435 on the bridge 416. The ears are used by the
9 pushing mechanism (not shown) to grasp the end of the clip when it
10 is loaded into the clip applicator. The clip 410 is applied to the
11 fundus in substantially the same way as described above with
12 reference to the clip 310. However, after the retainers 420, 422
13 are bent by the anvils and the jaws are opened, the clip 410 is
14 not released from the clip applicator and the retainers are separated
15 from the arms 412, 414. The resulting fastener formed by the
16 retainers 420, 422 is shown in Figure 23. This is actually two
17 substantially parallel "b" shaped fasteners. Thus, it may only be
18 necessary to apply a single retainer as shown in Figure 24, for
19 example.

20
21 There have been described and illustrated herein several
22 embodiments of methods and apparatus for the endoluminal treatment
23 of gastroesophageal reflux disease. While particular embodiments
24 of the invention have been described, it is not intended that the
25 invention be limited thereto, as it is intended that the invention

1 be as broad in scope as the art will allow and that the
2 specification be read likewise. It will therefore be appreciated
3 by those skilled in the art that yet other modifications could be
4 made to the provided invention without deviating from its spirit
5 and scope as so claimed.

(The page contains musical notation for the vocal parts.)